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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,982	04/25/2001	Scott L. Diamond	PENN0754	3650

26259 7590 05/22/2002

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/22/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,982

Applicant(s)

DIAMOND, SCOTT L.

Examiner

Richard Schnizer

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

An amendment was received and entered as Paper No. 9 on 4/26/02.

Applicant's election with traverse of group I, claims 1-13 is acknowledged. Traversal is on the grounds that the inventions are not novel and unobvious over each other as required by MPEP 802.01, and that there is no undue search burden on the Examiner. Applicant further argues that novelty over the prior art is not a consideration for restriction, relying on MPEP 806.01.

This Application was filed under 35 USC 371 as the national stage application of PCT/US99/20122, therefore restriction practice is carried out under the Administrative Rules for the PCT, rather than under the rules for US practice on which Applicant relies for support. Applicant is referred to 37 CFR 1.475(a) which deals with the determination of Unity of Invention before the International Searching Authority, the International Preliminary Examining Authority, and during the national stage, and which states:

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. **The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.**

Emphasis added. The technical feature linking the instant inventions cannot be a special technical feature because the technical feature linking the inventions does not provide a contribution over the prior art for the reasons of record in the restriction requirement. Applicant

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has failed to show otherwise. Furthermore, 37 CFR 1.475(a) does not allow for claims to more than one method of using an invention. Claim 14 corresponds to a second method of use of the claimed composition. For these reasons the restriction requirement is proper and is made FINAL.

Claim 14 is withdrawn from further consideration. Claims 1-13 are under consideration in this Office Action.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

The priority date for the instant application is considered to be 9/1/99, the date of filing of PCT/US99/20122.

Claim Objections

Claim 1 is objected to because it is ungrammatical. Specifically it recites the phrase "a eukaryotic cells". Either the word "a" should be deleted, or the plural "cells" should be made singular.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are indefinite because it is unclear what is intended by the term "enhancing". The claim requires a composition "for enhancing the delivery of a molecule to the nucleus of a cell". However, the claim sets forth no standard for comparison that would allow one of skill in the art to determine whether or not a composition provided enhanced delivery. Thus one cannot know the metes and bounds of the claim.

Claims 1-11 are indefinite because it is unclear what is encompassed by the phrase "nonclassical nuclear localization signal". The specification gives non-limiting examples of nonclassical nuclear localization signals at page 8, lines 9-11, and defines these examples as proteins which "do not interact with proteins such as importin alpha and importin beta". This definition fails to cover nonclassical nuclear localization signals which are not exemplified, thus one cannot know the metes and bounds of the phrase. Further, the definition itself is indefinite because the phrase "such as" makes it unclear with what proteins the nonclassical nuclear localization signals may and may not interact. See MPEP § 2173.05(d).

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Claims 7 and 8 are indefinite because it is unclear what is intended by "hydrolytic resistant". The claim requires a hydrolytic resistant chemical linkage, but it is unclear how the limitation "resistant" is intended to modify the claim. The specification fails to define the term resistant in this context, offering only non-limiting examples of hydrolytic resistant linkages. One of skill in the art cannot know the degree of resistance required by the claims because neither the claims nor the specification makes this clear. Thus one of skill in the art cannot know the metes and bounds of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Thatcher et al (WO 96/41606, published 12/27/99).

Thatcher teaches a composition comprising a cationic peptide scaffold (NBC2, see page 8, line 20), the nuclear localization targeting peptide encoded by SEQ ID NO:3 of the instant invention (M9, comprising the NLS of hnRNP A1, see page 92, lines 3-6), wherein the scaffold

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and the targeting peptide are conjugated by a hydrolytic-resistant linkage (see page 92, last full paragraph). The composition is useful in methods of transferring DNA to nuclei of cells and subsequently expressing encoded genes. See for example page 91, first paragraph. See also abstract; first page of summary; page 5, lines 8, 9, 20, 21, page 10, lines 7-9; page 20, lines 2-7; page 26, lines 16-20; page 32, lines 3-8; page 92, lines 1-4; and claim 22 on page 121.

Claims 1-7 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jans et al (Medicinal Research Reviews (1998) 18(4): 189-224).

Jans teaches that polypeptides comprising SEQ ID NO:3 may be chemically crosslinked to cationic DNA binding proteins for the purpose of delivering DNA to the nuclei of cells. See entire document, especially, page 192, lines 1-4 of second paragraph; pages 210 and 211, especially lines 8-14 of the first full paragraph on page 211; Fig. 2 on page 212; and paragraph bridging pages 214 and 215.

Conclusion

No claim is allowed. Claim 8 is free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.



JAMES KETTER
PRIMARY EXAMINER